DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

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March 23, 1992

R. William Soller, Ph.D.
Senior Vice President and
Director of Science and Technology
Nonprescription Drug Manufacturers
Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036

Dear Dr. Soller:

I am writing in response to your February 14, 1992 letter to Commissioner Kessler concerning the request made by Commissioner Mark Green of the New York City Department of Consumer Affairs that all hydroquinone-containing skin bleaching creams marketed over-the-counter (OTC) in the United States be seized and that further marketing of such products be banned. You requested that, before FDA takes any action on these products, (1) we reopen the administrative record for the OTC skin bleaching drug products rulemaking to allow NDMA time to submit information and (2) the meeting NDMA requested with the Center for Drug Evaluation and Research to discuss the National Toxicology Program (NTP) report on hydroquinone skin bleaching products be accomplished.

In response to your February 11, 1992, request to Dr. Botstein, our Center for Drug Evaluation and Research has already scheduled a meeting with your Association's Hydroquinone Task Group for April 8, 1992, to discuss the NTP study and your Task Group's research activities concerning the safety of hydroquinone. I have written Commissioner Green to inform him that this meeting is open to any interested party and to encourage representatives from his department to attend the meeting to listen to the discussion.

In addition, I have informed Commissioner Green that any decision on hydroquinone products is pending completion of our review of the data. Similarly, any decision regarding the reopening of the administrative record for the rulemaking for OTC skin bleaching drug products will be made after the meeting has been held and our review of the NTP study and related safety data on hydroquinone has been completed.

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We appreciate your comments and look forward to hearing the results of your meeting with the Center for Drug Evaluation and Research staff.

Sincerely yours,

Jane E. Henney, M.D.
Deputy Commissioner
for Operations